UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/091,578	10/06/98	MADISON E	19191.0002

HM12/0630

DAVID G PERRYMAN
NEEDLE & ROSENBERG
127 PEACHTREE STREET N E
SUITE 1200 THE CANDLER BUILDING
ATLANTA GA 30303-1811

EXAMINER	
DIBRINO,M	
ART UNIT	**PAPER NUMBER**
1644	7

DATE MAILED: 06/30/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/091,578	Madison et al
Examiner	**Group Art Unit**
Marianne DiBrino	1644

☒ Responsive to communication(s) filed on *Nov 24, 1998*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-64* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-64* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Group I, claims 1-24, drawn to a therapeutic/diagnostic agent.

II. Group II, claims 25-37, drawn to a recombinant targeting protein and a pharmaceutical composition thereof.

III. Group III, claims 38-45, drawn to nucleic acid encoding a recombinant targeting protein and nucleic acid that hybridizes to said nucleic acid.

IV. Group IV, claims 46, 47 and 48 drawn to a method of reducing a blood clot/preventing thrombosis/treating myocardial infarction in a subject using the protein of claim 33.

V. Group V, claim 49, drawn to a method of targeting a therapeutic compound to a tumor using the agent of claim 24.

VI. Group VI, claim 50, drawn to a method of targeting a compound to a tumor using the protein of claim 31.

VII. Group VIII, claim 51, drawn to a method of targeting a therapeutic protein to an osteoclast using the agent of claim 24.

VIII. Group VIII, claim 52, drawn to a method of targeting a therapeutic protein to an osteoclast using the agent of claim 31.

IX. Group IX, claim 53, drawn to a method of targeting a therapeutic compound to an endothelial cell using the agent of claim 24.

X. Group X, claim 54, drawn to a method of targeting a therapeutic compound to a tumor/tumor cell expressing αvβI integrin using the agent of claim 24.

XI. Group XI, claim 55, drawn to a method of targeting a therapeutic compound to a vascular smooth muscle cell using the agent of claim 24.

XII. Group XII, claims 56-64, drawn to a method of designing a targeted protein.

4. The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art. Lavie et al teach a targeted therapeutic agent comprising an anti-carcinoma monoclonal antibody conjugated to a drug. The therapeutic agent comprising a functinal entity linked to an isolated peptide mimetic which is based on an optimized high affinity polyamino acid of the instant claim 1 reads upon antibodies. Applicant has defined "peptide memetic" to include any chemical or inorganic molecule, the structure of which is based on or derived from a binding region of a protein (page 12, lines 7-9 of the specification) and has defined "polyamino acid" as a linear series of amino acid residues connected to the other as in a polypeptide (lines 1-2). The use of the open transitional phrase "comprising" in the instant claim reads upon sequences that include a linear series of amino acid residues, the structure of which is based on or derived from a binding region of a protein such as an antibody. It would have been obvious to manipulate the monoclonal antibody to optimize it's affinity.

Accordingly, Groups I-XII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

5. Irrespective of whichever group applicant may elect, applicant is further required under 35 U.S.C. 121 (1) to elect a single disclosed species (***a specific agent/protein***) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

For example, if the Invention of Group I is elected, applicant is required to elect a specific agent comprising a ***specific*** therapeutic or diagnostic functional entity linked to a ***specific*** peptide mimetic or a ***specific*** protein or a specific polyamino acid which binds a ***specific*** target.

These species are distinct because their physicochemical properties are different.

They are therefore separate and patentably distinct species in view of each other.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed

generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Marianne DiBrino

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
June 25, 1999
29

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600